

## REMARKS

### Present Status of Patent Application

Upon entry of the amendments in this response, claims 1, 3, 5, 8, 10-13, 15, 18-31, 33, 35-45, and 47 are pending in the application. Claim 1 has been amended herein, and claim 47 has been newly added.

The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims. Applicants respectfully request reconsideration and withdrawal of these objections and rejections for the reasons discussed below.

### Claim Rejections under 35 U.S.C. § 112

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, because claim 1 allegedly "recites the broad recitation of filter material having a pore size range in lines 9-12, and the claim also recites filter material with each specific type of material having a specific pore size which is the narrower statement of the range/limitation." *Office Action* at 2. Applicants have amended the claim to overcome the rejection.

### Claim Rejections under 35 U.S.C. § 103(a)

Claims 1, 3, 5, 8, 10-13, 15, 18-31, 33, and 35-45 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over *Yaremko et al.* (hereinafter "Yaremko") (U.S. Patent No. 5,620,898) in view of *Burshteyn et al.* (hereinafter "Burshteyn") (U.S. Patent No. 6,692,702). Applicants respectfully traverse the rejection.

Claim 1, as amended, reads in pertinent part as follows:

An immunological assay system, comprising:

a vessel capable of containing an assay sample and a reagent, wherein the **vessel comprises a bottom with an uneven surface, wherein the bottom of the vessel comprises a filter material** chosen from at least one of the following: polypropylene with 0.45 micron ( $\mu\text{m}$ )-sized pores; cellulose nitrate with 0.45  $\mu\text{m}$ -sized pores; nylon 6,6 with 0.45  $\mu\text{m}$ -sized pores; nylon 6,6 with 1.2  $\mu\text{m}$ -sized pores; HPVM membrane with 0.2  $\mu\text{m}$ -sized pores; polyvinylidene fluoride (PVDF) with 1.0  $\mu\text{m}$ -sized pores; PVDF with 1.2  $\mu\text{m}$ -sized pores; PVDF with 0.2  $\mu\text{m}$ -sized pores; and PVDF with 0.25  $\mu\text{m}$ -sized pores;

an image acquisition system in close proximity to the vessel, wherein the image acquisition system is designed to detect the presence of interactions between components in the assay sample and the reagent, wherein **said interactions are evidenced by agglutination, wherein the image acquisition system consists of a flow cytometer or a capillary cytometer...**

[Emphasis added]. Applicants respectfully submit that neither Yaremko nor Burshteyn, taken alone or in combination, teach at least the highlighted portions of claim 1 above.

In particular, Yaremko does not teach a vessel having a bottom with an irregular surface where the bottom comprises a filter material selected from one of the recited filter materials. Instead, Yaremko teaches a column filled with a gel or beads to act as a filter to help separate reactants based on size (Col. 1, line 40 to Col. 2 line 15 and Col. 6 lines 21-31). Thus, first the filter gel or beads of Yaremko do not comprise the bottom of the vessel, but fill the bottom portion of the microcolumn. Secondly, the gel or beads of Yaremko are completely different in both structure and function from the filter materials recited in the claims of the instant application. Burshteyn does not remedy the deficiencies of Yaremko in so far as the filter material of Burshteyn is also not on the bottom of a vessel. The filter material of Burshteyn is not even in the vessel 16; instead the filter material of Burshteyn forms a cylindrical tube 60 through which the sample passes, the filter material thus forming the sidewalls of the cylindrical tube/lumen 66. Thus, neither Yaremko nor Burshteyn disclose, teach or suggest, a reactant vessel having a bottom with an uneven surface and comprising a filter material chosen from the recited filter materials.

As discussed on page 11 of the specification, the filter material of the instant application serves a function of providing an irregular surface on the bottom of the vessel on which the reactants in the solution can spread out evenly for better analysis. In fact, at the claimed pore sizes, the instant specification notes that the filter material might not be effective at filtering liquids from the sample reactants. The specification further discusses this use of the filter material on page 7, lines 8-16, stating that no material is required to move through the filter; instead the filter provides an uneven topography to aid in separating the reacted components on the bottom of the vessel. Thus, the filter material differs significantly in both structure and function from the filter materials of Yaremko and Burshteyn, both of which are designed to separate the reactants based on size.

Furthermore, neither Yaremko nor Burshteyn disclose, teach, or suggest an immunological assay system where interactions between components in the assay sample are evidenced by agglutination, with a flow cytometer or a capillary cytometer. In Yaremko a camera is used to detect and distinguish the size of reactant particles based on size separation. And in Burshteyn, a flow cytometer can be used to detect fluorescence. Thus, neither reference discloses using a flow or capillary cytometer to detect agglutination.

Based on the foregoing, Applicants respectfully submit that Claim 1 is not obvious in view of the teachings of Yaremko and Burshteyn, either alone or in combination. Furthermore, independent claims 15, 23, and 39 also disclose an assay system having a vessel comprising a

bottom with an uneven surface, wherein the bottom of the vessel comprises a filter material as well as detecting interactions between components of the assay sample by detecting agglutination with a flow or capillary cytometer. Thus, claims 15, 23 and 39 are allowable for the same reasons set forth above for claim 1. Furthermore, claim 23 discloses the step of analyzing the reacted components on the bottom surface in the vessel with a flow cytometer, and claim 39 discloses the step of spreading the sample mixture over a bottom surface of a reaction vessel. Neither Yaremko nor Burshteyn disclose spreading or analyzing the sample on the bottom surface of the vessel. As discussed above, in Yaremko the sample is analyzed based on size distribution within the gel or bead "filter" material, and in Burshteyn, the mixture is sucked from the vessel through a filter "tube".

Because independent claims 1, 15, 23, and 39 are allowable, then for at least this reason, their dependent claims 3, 5, 8, 10-12, 18-22, 24-31, 35-38, and 40-46 are also allowable. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988). Applicants therefore respectfully request that the rejection of these claims be withdrawn as well.

#### New Claims 47-48

Applicants respectfully submit that new claim 47 includes all of the limitations of claim 1, and is therefore allowable for at least the reasons set forth above for claim 1. Furthermore, both claim 47 and claim 48 further disclose that the uneven surface of the vessel comprises filter material and that the filter material ***is configured to cause reacted components in the assay sample to spread out over the bottom surface of the vessel.*** As discussed above, neither Yaremko nor Burshteyn disclose, teach, or suggest a filter material such as the material of the instant claims that causes components of the assay sample to spread out over the bottom surface of the vessel.

#### Non-Finality of Office Action

Applicants acknowledge that the instant Office Action was not made final and thanks the Examiner for allowing Applicants another opportunity to argue the claims and/or place them in condition for allowance.

**CONCLUSION**

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Further, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known for at least the specific and particular reason that the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,

  
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